



Clarifying or Confirming the Extent of Process Exclusion under Art. 53(b) EPC?

Decisions G 2/12 and G 2/13 of the Enlarged Board of Appeal of the European Patent Office

Summary of EBA's Decisions

The Enlarged Board of Appeal (“EBA”) recently issued its joint decision on referrals G 2/12 and G 2/13—known as “Tomatoes II” and “Broccoli II”—clarifying the European Patent Office’s (“EPO”) position on the patentability of plants and plant parts in view of the process exclusion in Art. 53(b) EPC. These decisions assert the right of applicants to claim plants or plant parts such as fruit, in the form of product claims or product-by-process claims. The cases now have been remitted to the lower instance Technical Board of Appeal (“TBA”), whose deliberations continue.

Article 53(b) EPC excludes from patentability “plant ... varieties or essentially biological processes for the production of plants...”¹ In the first round of referrals, the EBA established the meaning of “essentially biological” in the context of traditional breeding, crossing, and selection of plants (G 2/07 and G 1/08: Tomatoes I and Broccoli I, respectively). In the second round of

referrals, the EBA’s task was to determine whether or not the exclusion of “essentially biological processes for the production of plants” extended to the products of those processes (i.e., plants or plant parts) and, if it did not, whether the fact that the product was defined only by process steps falling under the process exclusion would lead to an exclusion of such a product, especially where no other methods exist to make said product.

In construing Art. 53(b) EPC, the EBA concluded that the intention of the legislator had been to allow the patenting of plants (or plant parts) using product claims. Had the legislator intended otherwise, it would not have used differing terminology in the first and second parts of Art. 53(b), i.e., “*plant varieties*” in contrast to “... processes for the production of *plants*...” The EBA made a clear distinction between process claims (which protect a method of doing or making something) and product-by-process claims (which protect a product per se but describe it by the way it is produced or obtained) and reasserted that process steps in a product-by-process

claim are not protected and that the product itself must meet the usual criteria of patentability.

The decisions come as a relief to the numerous applicants and patentees of inventions related to plants and plant products, the fate of whose applications and patents had been uncertain. These decisions seem to confirm established patent practice rather than setting new precedents in this field of technology. Innovators in plant technology, i.e., seed, horticulture, and ornamental plant breeders and growers, will now have the legal certainty to carry on their research and plan their IP strategy knowing they are eligible to obtain patent protection.

Background

The cases underlying the referrals to the EBA are two appeals referred up from opposition proceedings, T 1242/06 and T 83/05.

T 1242/06 (“Tomatoes”) concerns European Patent No. 1211926, granted for a method of breeding tomatoes having reduced water content and a tomato product capable of natural dehydration. The method comprises a step wherein the fruit is allowed to remain on the vine past the point of normal ripening in order to be screened and selected for increased dry weight percentage. In opposition proceedings, the patent was maintained in amended form, following which the decision was appealed by both the patent proprietor and the opponent.

T 83/05 (“Broccoli”) concerns European Patent No. 1069819, granted for a method of crossing *Brassica* species to increase anticarcinogenic glucosinolates followed by selection of hybrids with increased levels of the glucosinolates using molecular markers. The patent claims the crossing and selection method of a *Brassica* plant, a part of the plant, or a seed thereof, where the plant was produced according to the method or by a hybrid crossing. As with Tomatoes, the patent was maintained in amended form in opposition proceedings. The decision was appealed only by the opponents.

In view of the issues raised during opposition proceedings, and which subsisted during appeal proceedings, the TBA (No. 3.3.04) made its first referrals (G 1/08–Tomatoes I and G2/07–Broccoli I) to the EBA, requesting guidance on how to interpret the exclusion of essentially biological processes for the production of plants established in Art. 53(b) EPC.

The First Referrals to the EBA. The first referrals concerned the expression “... *essentially biological* processes for the production of plants ...” in Art. 53(b) EPC and corresponding Rule 26(5) EPC, which defines that “[a] process for the production of plants ... is essentially biological if it consists entirely of natural phenomena such as crossing and selection.” The ambiguous wording created uncertainties in the application of these provisions. Thus, the TBA sought clarification on the meaning of the exclusion of non-microbiological processes for the production of plants, which contains the steps of crossing and selection and asked: (i) whether such a process falls under the exclusion of Art. 53(b) EPC only if these steps reflect and correspond to phenomena that could occur in nature without human intervention; (ii) whether, to escape the exclusion from patentability in Art. 53(b) EPC, it is enough to have, as a further step or as part of any of the steps of crossing and selection, an additional feature of technical nature; and (iii) what are the criteria to establish whether or not such a process falls under the exclusion of Art. 53(b) EPC. In other words, is it of relevance where the essence of the invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

Given the similarity of the referrals, the EBA considered cases G 1/08 and G 2/07 together in consolidated proceedings. The EBA decided that the exclusion under Art. 53(b) EPC applies to non-microbiological processes for the production of plants that comprise or consist of steps of sexually crossing the *whole genome* of plants and their subsequent selection.

Such processes are excluded by virtue of Art. 53(b) EPC, even in the presence of a technical step as a further step or as part of any of the steps of crossing and selection, which enables or assists in sexually crossing the whole genomes of plants or their subsequent selection. Because the exclusion is policy driven, the standard criteria of patentability do not apply; any technical step (e.g., the use of molecular markers for selecting a specimen with the desired traits), whether novel and inventive, will not render the process patentable if the step is only related to the crossing of the *whole genome* and subsequent selection. However, a technical step may render a process patentable if that technical step itself modifies the genome beyond that which would occur from any sexual crossing of the whole genome. In the words of the EBA:

If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC. (G 1/08, Order 3).

Following the EBA's decisions in G 1/08 and G 2/07, the cases were remitted to the TBA, where proceedings were resumed and the patent proprietors deleted the process claims that, in light of the EBA's rulings, would likely have been considered unpatentable for claiming essentially biological processes for the production of plants. The remaining patent claims in Tomatoes were directed to tomato fruit (products), and in Broccoli the remaining claims were of the product and product-by-process type. The TBA now had to consider the patentability of these product and product-by-process claims.

The Second Referrals to the EBA. Following the patentees' submission of new claim sets containing only product and product-by-process claims, the TBA referred new questions to the EBA on the interpretation of the Art. 53(b) EPC exclusion—this time on the effect of the process exclusion on the patentability of *products* obtained from such processes (referrals G 2/12—Tomatoes II and G 2/13—Broccoli II).

In Tomatoes II, the opponent argued that protection of the plant material (tomato fruit) would necessarily also encompass the essentially biological processes used by breeders to obtain such plants. Allowing such product claims would frustrate the legislator's intent to exclude essentially biological processes from patent protection, as was determined in G 1/08 and G 2/07. Hence, the exclusion of essentially biological processes for the production of plants should necessarily extend to the products of such processes. The issues raised in Broccoli II were largely similar.

Having considered this point, the TBA indicated that such product claims would not be excluded as plant varieties under Art. 53(b) EPC. Nevertheless, they were concerned that allowing these claims might render the exclusion to essentially

biological processes ineffective, since these products would be produced by such a method.

In view of the issues raised in both cases, the TBA referred its questions to the EBA. In Tomatoes II (G 2/12), the TBA asked the following:

1. Can the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC have a negative effect on the allowability of a product claim directed to plants or plant material such as a fruit?
2. In particular, is a claim directed to plants or plant material other than a plant variety allowable even if the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application?
3. Is it of relevance in the context of questions 1 and 2 that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53(b) EPC?

The questions referred by the TBA in Broccoli II were similar to those in Tomatoes II, with two differences—the Broccoli patent claimed a plant part rather than just a fruit, and it used the product-by-process format to claim the invention. Additionally, the issue of using disclaimers² to exclude the process per se was mooted:

1. Can the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC have a negative effect on the allowability of a product claim directed to plants or plant material such as plant parts?
2. In particular:
 - (a) Is a product-by-process claim directed to plants or plant material other than a plant variety allowable if its process features define an essentially biological process for the production of plants?

(b) Is a claim directed to plants or plant material other than a plant variety allowable even if the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application?

3. Is it of relevance in the context of questions 1 and 2 that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53(b) EPC?

4. If a claim directed to plants or plant material other than a plant variety is considered not allowable because the plant product claim encompasses the generation of the claimed product by means of a process excluded from patentability under Article 53(b) EPC, is it possible to waive the protection for such generation by “disclaiming” the excluded process?

Decisions of the EBA

In view of the similarity of issues being dealt with in the second round of referrals, the EBA decided once again to consolidate proceedings. The EBA invited the patent proprietors, the opponents of the Broccoli patent, and the president of the EPO to file comments on the referrals.

Briefly, the proprietor of the Tomatoes patent argued that the referral should be deemed inadmissible in view of G 1/98, which established that only product claims directed to plant *varieties* are excluded from patentability under Art. 53(b) EPC. In case the referral was admissible, then G 1/08 and G 2/07 should be revised to exclude only processes that result directly in a plant *variety*.

The proprietor of the Broccoli patent argued that decisions G 1/08 and G 2/07 should be revised since they lead to a second referral. Additionally, the proprietor argued that the process exclusion should be interpreted narrowly, and therefore it should not extend to product claims. Interestingly, the opponents in the Broccoli case argued that questions 1, 3, and 4 should be answered in the negative and question 2,

in principle, in the affirmative. The opponents further noted that to exclude plants, which are obtainable by an essentially biological process, would result in nothing being patentable in the plant world.

Finally, the president of the EPO submitted that Art. 53(b) EPC did not have a negative effect on the allowability of product claims on plants. In addition to the above considerations, numerous *amicus curiae* briefs raising concerns on economical, social, ethical, and political levels were filed by plant breeders groups, politicians, and individuals.

The EBA stated that G 1/98 dealt with the exclusion of plant varieties in Art. 53(b) EPC, without addressing the *extent* or *scope* of the exclusion of essentially biological processes to products. Thus, the referrals were necessary to provide a uniform application of the law. Furthermore, the EBA decided that there was no need to review decisions G 1/98, G 2/07, or G 1/08, because the instant referred questions concerned only the *legal scope* of the process exclusion under Art. 53(b) EPC and its impact on the patentability of product claims and product-by-process claims: i.e., whether the exclusion extends to plant material directly obtained and/or defined by an “essentially biological process.”

In answering the referred questions, the EBA methodically construed Art. 53(b) EPC mainly using the principles of interpretation established in Art. 31 and 32 of the Vienna Convention. It began its analysis by focusing on the wording of the provision (grammatical interpretation), followed by systematic and teleological interpretations. It then continued the analysis from the perspective of subsequent agreements or practice and finally considered the legislator’s intent (historical interpretation).

Based on its analysis, the EBA concluded that the exclusion of “essentially biological processes for the production of plants” does not extend to products defined or obtained by such processes. That is, the EBA found no basis for a broad reading of the process exclusion of Art. 53(b) EPC in respect of product or product-by-process claims directed to plants or plant parts such as fruit. In this respect, the EBA also stated that subject-matter claimed as a product or a product-by-process is different from that claimed as a process, regardless of the methods

by which the claimed product is obtained or defined. Also, even if the product (plant material) can be obtained only by essentially biological processes, the process exclusion in Art. 53(b) EPC does not extend to product or product-by-process claims. Whether such products or products-by-process are patentable depends on fulfillment of the formal and substantive patentability requirements of the EPC.

The EBA addressed certain interesting issues that were raised in the *amicus curiae* briefs: Interest groups claimed that the legal impact of Art. 53(b) EPC (as it was then interpreted) required extending the scope of the process exclusion to avoid the unintended monopolization of unpatentable processes.

One issue addressed by the EBA was the need to account for technological progress, which might lead to circumvention of the exclusion. The EBA considered whether there was a need for a “dynamic interpretation” of Art. 53(b) EPC, taking into account evolving technologies that could not have been foreseen by the legislator and extrapolating their intent based on current technologies. They concluded that no dynamic interpretation of Art. 53(b) EPC was required and that the process exclusion should not extend to products obtained by essentially biological processes for the production of plants despite advances in technology.

The EBA also considered whether the allowance of product and product-by-process claims directed to plants or plant material renders the process exclusion meaningless in its scope of application. The EBA stated that it did not see any imminent legal erosion of the exclusion of essentially biological processes and left product and product-by-process claims outside the scope of the process exclusion.

Comments on Decisions

In deciding the two rounds of referrals, the EBA performed an extensive and elaborate analysis of Art. 53(b) EPC, taking into consideration its legal context, including its legal and historical background, as well as different sources of interpretation. Decisions G 2/07 and G 1/08 were controversial because the parties considered that the exclusion in Art. 53(b) EPC had been interpreted broadly. In contrast, decisions G 2/12 and

G 2/13 appear to have caused less controversy due to the narrower construction and the explicit distinction made between exclusions from patentability, patentability requirements (e.g., novelty, inventive step, etc.), and scope of protection.

One interesting issue raised during the appeal proceedings was whether patenting a plant or plant material that is produced by an “essentially biological” process might be counter to the legislative intent of the exclusion in Art. 53(b). In this context, the TBA questioned whether it is relevant that the protection conferred by a product claim to a plant encompasses the generation of the claimed product by means of an essentially biological process, as excluded under Art. 53(b) EPC. That is, would the patentee obtain forbidden process protection by virtue of his product claim?

In referring this issue, the TBA made three observations. First, that Art. 64(2) EPC³ extends the protection of a process claim to products directly obtainable by said process. Second, that protection conferred by product claims also covers using and making the product, and third, that the protection of a product-by-process claim extends to identical products produced by a different method.

The EBA took issue with the reference to Art. 64(2) EPC, which was cited in the context of assessing patentability, when in fact Art. 64(2) EPC is concerned with the protection conferred by a process claim once granted. The EBA, recognizing that pre- and post-grant issues were being conflated, clarified that: “the relevant point of law ... is whether or not the ‘subject-matter’ of a product claim or product-by-process claim ... is excluded from being patented under Article 53(b) EPC by virtue of the essentially biological nature of the process for making said plant or plant material,” or rather, that the scope of protection of a claim is immaterial to the pre-grant assessment of patentability.

On this point, the EBA referred to G 1/98 (in which it was decided that Art. 64(2) EPC must not be considered when assessing the patentability of a claim to a process for the production of a plant variety) and decided that this principle applies *mutatis mutandis* to the examination of product or product-by-process claims directed to plants or plant material.

Consequently, even if the “product” of a product-by-process claim is obtainable by (or may be obtained only by) an essentially biological process, the claim is allowable despite the potential unintended monopolization of the process. Patentees will certainly welcome the consistent application of principles by the Boards, particularly as it keeps the doors open for patenting valuable plant technology.

Conclusions

The referrals dealt with different aspects of the patentability exclusion established in Art. 53(b) EPC, and taken together, decisions G 2/07 / G 1/08 and G 2/12 / G 2/13 (along with G 1/98) provide users of the European patent system with clarity and certainty on the limits of patentability of plants, plant material, and related methods of producing plants.

Decisions G 2/07 and G 1/08 established that methods for the production of plants based on the crossing of whole genomes are excluded from patentability regardless of any additional step that would (merely) assist the activity of crossing or selecting. By implication, methods for the production of plants based on engineering one or more specific genetic traits into a target plant’s genome are patentable.

Decisions G 2/12 and G 2/13 confirmed that plant material (e.g., plants, plant parts, or fruit) are patentable and may be claimed as products per se or as products-by-process. The patentability of such claims depends only upon their compliance with the standard requirements for product claims (novelty, inventive step, etc.) and not on any aspect of their method of production.

Lawyer Contacts

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Endnotes

- 1 Article 53(b) EPC. Exceptions to patentability. “European patents shall not be granted in respect of: (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof”
- 2 A disclaimer is a limitation of claimed subject-matter in the form of a negative statement that defines the absence of a particular feature. Specific conditions for the allowability of disclaimers according to European patent practice are given by case law. (See Guidelines for Examination in the European Patent Office, Part F IV, 4.20.)
- 3 Article 64(2) EPC. Rights conferred by a European patent. “If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.”